

IN THE CLAIMS

Claims 1-15 (canceled)

16. (previously presented) A controlled release melatonin tablet which comprises:

(a) a slow release nucleus comprising melatonin, hydroxypropylmethylcellulose, a lubricant, a volume excipient and a glidant, wherein 95% of the melatonin is released within 5 hours in an oscillating tray containing gastric/intestinal juice at 37°C;

b) a fast release cortex coating on said nucleus which comprises melatonin, hydroxypropylmethylcellulose, a lubricant, a volume excipient and a glidant, wherein at least 95% of the melatonin is released within 10 minutes in an oscillating tray containing gastric/intestinal juice at 37°C.

17. (previously presented) The melatonin tablet as defined in claim 16 which comprises:

(a) a slow release nucleus comprising from 1 to 3 mg of melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant;

(b) a fast release cortex coating on said nucleus which comprises 0.5-1.5mg of melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant.

18. (previously presented) The melatonin tablet as defined in claim 16 which consists essentially of:

(a) a slow release nucleus consisting essentially of melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant;

(b) a fast release cortex coating on said nucleus which consist essentially of melatonin, hydroxypropyl methylcellulose, a volume excipient and a glidant.

19. (canceled)

20. (previously presented) The melatonin tablet as defined in claim 16 which consists essentially of:

(a) a slow release nucleus consisting essentially of 1-3 mg of melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant;

(b) a fast release cortex coating on said nucleus which consists essentially of 0.5-1.5 mg of melatonin with hydroxypropyl methylcellulose, a volume excipient and a glidant.

21. (previously presented) The melatonin tablet as defined in claim 16 which comprises:

(a) a slow release nucleus comprising melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant;

(b) a fast release cortex coating on said nucleus comprising melatonin, hydroxypropyl methylcellulose, a volume excipient and a glidant wherein said tablet provides a maximum plasma level of 1,000 to 2,000 pg/ml of melatonin upon in vivo administration.

22. (previously presented) A controlled release melatonin tablet which comprises:

(a) a slow release nucleus comprising melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant which releases the melatonin over a 5 to 7 hour period in vivo;

(b) a fast release cortex coating on said nucleus comprising melatonin, hydroxypropylmethylcellulose, a volume excipient and a glidant which releases the melatonin in 5-10 minutes in vivo.

23. (previously presented) A method of inducing and maintaining sleep which comprises the administration of the formulation of claim 16 to one who suffers from a sleep

disorder.

24. (previously presented) A method of inducing and maintaining sleep which comprises the administration of the formulation of claim 20 to one who suffers from a sleep disorder.